Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
973-286-6700
clizza@saul.com

Attorneys for Plaintiff
Celgene Corporation

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. LOTUS PHARMACEUTICAL CO., LTD. and ALVOGEN PINE BROOK LLC, Defendants.	Civil Action No. 17-6842 (SDW)(LDW) **(Filed Electronically)**

PLAINTIFF CELGENE CORPORATION'S OPPOSITION TO DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS

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I. INTRODUCTION

Celgene Corporation ("Celgene") is a biopharmaceutical company committed to improving the lives of patients worldwide by focusing on, and investing heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions, including cancer. But several of Celgene's life-prolonging cancer drugs have the potential to cause severe birth defects. Before Celgene could bring these drugs to market, it had to develop a method of protecting unborn children. Celgene invented computerized methods and systems using a centralized computer-readable storage medium that is specifically configured to prospectively assess the likelihood of harmful side effects and to generate a prescription approval code only if that risk is sufficiently low, so as to allay the risk of fetal exposure to the drugs. Celgene's novel system (known as a "REMS" under FDA regulations) thus removes a doctor's autonomy, can override his or her decision to issue a prescription, and has successfully prevented birth defects for more than 20 years.

Lotus argues that the REMS Patents are unpatentable under 35 U.S.C. § 101 under the two-part framework established by the Supreme Court in *Alice Corp. Pty. v. CLS Bank Int'l.*, 134 S. Ct. 2347 (2014). Under the first part of the *Alice* test, Lotus argues that the patents covering Celgene's REMS are directed to an abstract idea. But Lotus's argument rests upon a fundamentally improper and overly simplistic characterization of the patents' claims. In support of its motion, Lotus reduces the 147 detailed claims of Celgene's five REMS Patents to just the phrase "restricting access to a pharmaceutical by patients who may be harmed by the drug," and then decrees that this undue simplification describes a patent-ineligible abstract idea. D.I. 69-1 at 6. But under Lotus's reasoning, every method-of-use patent would be patent-ineligible because it can be reduced to an abstraction. For example, Lotus's approach would reduce all patents claiming innovative ways to cure medical conditions to "treating a patient's disease with

a drug," and declare them abstract. This results-driven methodology has been rejected by the Federal Circuit and does not render Celgene's inventions abstract. Further, Lotus's reductionist interpretation of the REMS Patents ignores and eliminates the defined improvements to computerized system functionality that are at the heart of the claimed inventions.

Lotus also fails to show that Celgene's REMS Patents would preempt any abstract ideas. Even following Lotus's reductionist analysis, there are many ways of "restricting access to a pharmaceutical." In fact, there are 71 other FDA-approved REMS, several of which are covered by their own patents. Under Lotus's theory, however, those other REMS and REMS patents would cover methods of "restricting access to a pharmaceutical by patients who may be harmed by the drug," except with very different ways of protecting patients that are not preempted by Celgene's REMS Patents.

Lotus's analysis under the second part of the *Alice* test is equally flawed. Even if the claims of Celgene's REMS Patents were directed to an abstract idea (which Celgene disputes), they remain patent eligible because they recite specific, discrete implementations of the idea. The claimed elements of a system utilizing a centralized computer-readable storage medium that is specifically configured to generate a prescription approval code are neither routine nor conventional. Rather, they improve upon problems in the art concerning the safe administration of dangerous drugs.

Finally, even if Lotus's motion had any merit (it does not), it is premature. Disputes exist between the parties as to fact issues and claim construction that render judgment on the pleadings at this early stage—prior to the development of a full record—inappropriate. Both the Federal Circuit and this District's precedent counsel against granting Lotus's motion at this time, particularly where Lotus's motion pertains to less than one third of the patents-in-suit.

For the foregoing reasons, and as described further below, Lotus's motion should be denied.

II. LEGAL STANDARD

The question of patent-eligibility under 35 U.S.C. § 101 is a two-step inquiry. "First, the court looks to whether the claims are directed to patent ineligible subject matter, like laws of nature, natural phenomena or abstract ideas." *Rutgers v. Qiagen N.V.*, No. 15-7187, 2016 WL 828101, at *2 (D.N.J. Feb. 29, 2016) (citing *Alice*, 134 S. Ct. at 2354). "Second, the court must determine whether the application is patent-eligible, by considering 'the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application.'" *Rutgers*, 2016 WL 828101, at *2 (citation omitted). Addressing either step, even when deciding a motion to dismiss on the pleadings, requires the Court to "examine the claims in light of the written description." *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1299 (Fed. Cir. 2016).

Patent eligibility is "a question of law which may contain underlying facts." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). Judgment on the pleadings is appropriate only in very limited circumstances—specifically, "only when there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law." *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018). As such, the Federal Circuit has instructed that "it will ordinarily be desirable—and often necessary—to resolve claim construction disputes prior to a § 101 analysis, for the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter." *BanCorp Servs., LLC v. Sun Life Assurance Co. of Canada,* 687 F.3d 1266, 1273-74 (Fed. Cir. 2012).

"If the Court is going to invalidate [the patents-in-suit] on subject matter eligibility grounds before claim construction, then ***Defendants must 'establish*** that the only plausible

construction [i]s one that, by clear and convincing evidence, render[s] the subject matter ineligible (with no factual inquiries).'" *Data Distribution Tech., LLC v. Brer Affiliates, Inc.*, No. 12-4878, 2014 WL 4162765, at *6 (D.N.J. Aug. 19, 2014) (emphasis added) (citation omitted). "Accordingly, it will be rare that a patent infringement suit can be dismissed at the pleading stage for lack of patentable subject matter." *WAG Acquisition, LLC v. Multi-Media, LLC*, No. 14-2340, 2015 WL 5310203, at *5 (D.N.J. Sept. 10, 2015) (quotation omitted). Indeed, "[a]ny fact . . . that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence." *Berkheimer*, 881 F.3d at 1368.

III. ARGUMENT

A. Lotus Fails to Prove That The REMS Patents Claim An Abstract Idea

At step one of the analysis, Lotus must establish that the claims at issue are directed to an abstract idea. Claims are not abstract if they are "directed to a specific improvement" or "to a specific implementation of a solution to a problem." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1338-39 (Fed. Cir. 2016). Similarly, "[c]laims directed to a 'new and useful technique' for performing a particular task [are] not abstract." *Local Intelligence, LLC v. HTC Am., Inc.*, No. 17-cv-6437, 2018 WL 1697127, at *4 (N.D. Cal. Apr. 6, 2018) (citation omitted).

1. Lotus Has Improperly Oversimplified The REMS Patents

When "conducting the step one analysis, courts should not 'oversimplif[y]' key inventive concepts or 'downplay' an invention's benefits." *Pac. Biosciences of California, Inc. v. Oxford Nanopore Techs., Inc.*, No. 17-1353, 2018 WL 1419082, at *4 (D. Del. Mar. 22, 2018) (quoting *Enfish*, 822 F.3d at 1337-38) (alteration original). Yet this is ***precisely*** what Lotus asks this Court to do. Lotus's motion rests on its assertions that the REMS Patents are all directed to "the abstract idea of restricting access to pharmaceuticals by patients who may be harmed by the drug;" that the "patents describe no new technology or improvement to computer functionality;"

and that "every step in each of the claims could be performed by a healthcare professional equipped with only a pen and paper." D.I. 69-1 at 6-7. But these litigation-driven oversimplifications willfully ignore that the REMS Patents claim improved methods and systems specifically designed to improve computerized means of drug distribution.

(a) The Inventions Are Directed To A Specific Technological Improvement And Are Therefore Not Abstract

Each of the REMS Patents is directed to "improved methods for delivering a drug to a patient." *See* '720 Patent at 1:8-9.[1] The claimed and "novel methods permit the distribution to patients of drugs, particularly teratogenic drugs, in ways wherein such distribution can be carefully monitored and controlled." *See id.* at 1:13-16. In this way, the REMS Patents claim far more than "a fundamental concept in the practice of medicine and pharmacy," as Lotus contends. *See* D.I. 69-1 at 16. Each of the REMS Patents claims novel methods or systems for monitoring and controlling the distribution of teratogenic drugs, ***through the use of explicitly defined improvements to existing computer system functionality***. The specification of each REMS Patent sets forth that "improvements" to known methods of computerized drug distribution would be "useful," and then describes defined methodologies for solving problems in the art. *See, e.g.*, '720 Patent at 1:65-2:12 (explaining that while the prior art "provides methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug . . . [i]mprovements to this method may be useful, however, to minimize and simplify the demands on the pharmacy, thereby improving compliance with the system of distribution, and reducing the risk that the drug will be dispensed to a contraindicated individual").

[1] For convenience, Celgene cites to the specification of the '720 Patent—attached as Exhibit B to the Complaint—throughout this brief. As Lotus agrees, "[e]ach of the other REMS Patents have equivalent disclosures." D.I. 69-1 at 8 n.4.

The asserted claims of the REMS Patents improve upon the function of computerized systems in a very specific way: by requiring the generation of a specific prescription approval code from a specific "computer readable storage medium" or "computer readable medium." Celgene proposes that the "prescription approval code" means a computer "code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable." Celgene further proposes that the specific "computer readable [storage] medium" means "a centralized database that includes all registration information regarding the claimed prescribers, pharmacies, and patients." The centralized computer databases of the claimed inventions are designed to store and process information regarding ***all*** prescribers, distributors, and users of the particular drug at issue.

The improvements claimed in the REMS Patents allow for the system to override a doctor's autonomy. Specifically, the specifications explain that the centralized computer readable storage medium will generate a prescription approval code (thereby allowing for a prescription to be dispensed) ***only if*** it determines, based upon all stored information, that the benefit of dispensing the drug to the patient outweighs the risk. *Id.* at 13:45-49. The specifications of the REMS Patents describe the generation of the claimed prescription approval code from the computer readable storage medium as an improvement upon existing computer technology. *See, e.g.*, *id.* at 2:40-45 (setting forth that "***a system is needed*** for the controlled distribution of a drug, in which [ ] all users of the drug, including prescribers, pharmacies, and patients, may be accountable for their compliance with methods that may be established to minimize the risk that a contraindicated individual will be exposed to the drug") (emphasis added).

In this respect, the REMS Patents claim more than abstract methods of "restricting access" to a drug. The patents instead claim defined methods and systems that utilize an improved centralized computer network, thereby allowing the manufacturer of a drug (or other administrator of the system) to monitor distribution to all doctors, pharmacies, and patients and, as appropriate, to override a doctor's decision to issue a prescription based upon a prospective risk assessment based upon all known information, including information unavailable to the prescribing physician. *See id.* at 13:19-30 ("The registration into one or more computer readable storage media of the prescriber, pharmacy and patient, according to the methods described herein, provide a means to monitor and authorize distribution of contraindicated drugs, including teratogenic drugs."); *see also id.* at 3:5-10 ("The improved methods described herein provide advantageous and effective means for monitoring, controlling and authorizing the distribution to patients of drugs known or suspected of causing adverse side effects.").

The facts present here are similar to those in *Enfish*. There, the Federal Circuit reversed the district court and held that similar claims reciting an improved database constituted a technological improvement and, thus, were ***not*** directed to an abstract idea. 822 F.3d at 1338-39. Specifically, the Federal Circuit held that claims directed to a "self-referential" database were patent eligible under Section 101. *Id.* at 1329. As an initial matter, the court noted that "improvements in computer-related technology" and "claims directed to software" are not "inherently abstract," and may be resolved at the first step of the *Alice* analysis. *Id.* at 1335. Applying that reasoning to the claims before it, the court held that the "plain focus" of the claimed database "is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity." *Id.* at 1336.

The district court's error in *Enfish* mirrors what Lotus asks this Court to do here. Specifically, the district court erred in *Enfish* by characterizing the claims as simply "storing, organizing, and retrieving memory in a logical table," *see id.* at 1337, and here, Lotus contends that "the claimed methods are clearly directed to the basic steps of collecting, categorizing, and analyzing data." *See, e.g.*, D.I. 69-1 at 17.[2] The Federal Circuit in *Enfish* explained that "describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule." 822 F.3d at 1337. Because the claimed database was "a specific type of data structure designed to improve the way a computer stores and retrieves data in memory," the court concluded that the claims "are directed to a specific implementation of a solution to a problem" rather than an abstract idea. *Id.* at 1339.

Similarly here, the claims of the REMS patents are directed to a system utilizing a central computer readable storage medium specially configured to generate prescription approval codes through interrelating patient, prescriber, and pharmacy data. Lotus has no evidence that this was known in the art; it was not. Lotus also has no evidence that this was not an improvement upon pre-existing, prior art system functionality; it was. The claimed methods of generating prescription approval codes inventively improve upon computer system function, easing administrative burdens on healthcare providers, which increases patient safety by achieving greater and more efficient compliance with the REMS. *See* '720 Patent at 13:57-64. The

[2] Accordingly, Lotus's reliance on *Smart Sys. Innovations, LLC v. Chicago Transit Auth.*, 873 F.3d 1364 (Fed. Cir. 2017), *Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343 (Fed. Cir. 2014), and *In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607 (Fed. Cir. 2016) is misplaced. The claims of the REMS Patents are directed to methods that involve more than the collection, categorization, storage, or even recognition of data. To the contrary, the REMS Patents solve a problem inherent in the data systems that existed at the time of invention by creating a centralized computer medium capable of generating prescription approval codes.

prescription approval code generated by the centralized computer readable storage medium is a specific solution to a problem in the art, not an abstract idea.[3]

Lotus argues that "[p]resenting the results of the [centralized computer storage medium's] analysis via a prescription approval code . . . does not render the claims any less abstract." *See* D.I. 69-1 at 18 (citing *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905 (Fed. Cir. 2017); *Elec. Power Grp. v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016)). Lotus is incorrect, because it overlooks that the patents at issue in both *Secured Mail* and *Elec. Power Grp.* failed to claim any new or improved means of computer functionality. *See Secured Mail*, 873 F.3d at 910 ("the claims of Secured Mail's patents are not directed to an improvement in computer functionality"); *Elec. Power Grp.*, 830 F.3d at 1355 ("The claims in this case do not even require a new source or type of information, or new techniques for analyzing it.") But here, the REMS Patents each claim an improvement to computer function. Prior systems were not centralized, and healthcare providers consulting those systems had to perform their own risk assessments, often based on incomplete information. The REMS Patents, on the other hand, claim methods that improve upon known system functionality by creating a ***central*** computer that is capable of assessing patient risk and communicating the results of that assessment to healthcare professionals by generating a unique approval code. Lotus has presented no evidence to the contrary.

Moreover, Supreme Court precedent confirms that the types of claims recited in the REMS Patents are not foreclosed by Section 101. For example, in *Diamond v. Diehr*, the Supreme Court found that claims directed to using a computer to automate the process of curing

[3] As discussed further below, Lotus has not agreed to Celgene's proposed construction of "computer readable storage medium," thus rendering the § 101 analysis premature.

rubber were patent eligible. 450 U.S. 175, 191 (1981).[4] Although the underlying formula was well known and the remaining steps of the claims—such as installing rubber in a press, closing the mold, determining the temperature of the mold, and opening the press—were not themselves novel, the Supreme Court found that the combination of these elements constituted a specific process for molding rubber and not an attempt to patent an abstract idea. *Id.* at 187. The Court recognized that "one does not need a 'computer' to cure natural or synthetic rubber, but if the computer use incorporated in the process patent significantly lessens the possibility of 'overcuring' or 'undercuring,' the process as a whole does not thereby become unpatentable subject matter." *Id*. Precisely the same can be said of the claims of the REMS Patents. Like the claims in *Diehr*, the asserted claims are directed to specific processes that use a specially designed central computer database to generate prescription approval codes, which improves detection and prevention of the risks associated with teratogenic drugs. Although other methods of reducing the risks of prescription drugs may be possible without the use of a central computer database designed to generate prescription approval codes, that fact alone does not render the claims patent-ineligible.

Likewise, in *In re Alappat*, the Federal Circuit held that claims directed to an algorithm for generating smooth waveforms on an oscilloscope display were patent eligible. 33 F.3d 1526, 1543-44 (Fed. Cir. 1994), *abrogated on other grounds*, *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008). The court recognized that the claims recited only mathematical operations and structures "known in the electronics arts before Alappat made his invention." *Id.* at 1539. Nevertheless, the court held that the claimed invention "is not a disembodied mathematical concept which may be characterized as an 'abstract idea,' but rather a specific machine to produce a useful, concrete,

[4] The Supreme Court recently reexamined *Diehr* in *Alice* and reaffirmed its prior holding. 134 S. Ct. at 2358.

and tangible result." *Id.* at 1544. The court rejected the argument that the claims were patent-ineligible because they could be implemented on a general-purpose computer, holding that "a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software." *Id.* at 1545. Like the claims in *Alappat*, the claims of the REMS Patents are directed to a specially configured computer, specifically designed to generate the prescription approval code through the centralized computer readable storage medium. The claims, therefore, involve a special purpose computer, not a general-purpose computer.

Claims "directed to an improvement to computer functionality" are not abstract. *Enfish*, 822 F.3d at 1335. Instead, where "the plain focus of the claims is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity," the claims are deemed patent eligible under step one of the eligibility inquiry. *Id.* at 1336. The inventive methods claimed in the REMS Patents solve the problems associated with prior art computerized drug distribution systems by improving computer function in a very specific way: by generating prescription approval codes only after a complete risk assessment has been performed by a central computer. This innovation improved upon the computer systems that were known in the art, and it was specifically designed to solve problems with those existing systems. Lotus has presented no evidence to the contrary. The REMS Patents' inventions are not abstract. To the contrary, the REMS Patents claim "a specific way to solve a specific problem." *Agri-Labs Holding LLC v. Taplogic, LLC*, 304 F. Supp. 3d 773, 786 (N.D. Ind. 2018). They do "not claim the ends sought, but rather claim[] the means of achieving those ends." *Id.* Lotus therefore cannot meet its burden.

The Supreme Court has recognized that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012). But, the mere use of an abstract idea does not render an invention patent ineligible, as long as it is an "application . . . to a new and useful end." *Alice*, 134 S. Ct. at 2354 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). The same rule applies for patents that claim a computer-implemented method: the mere use of a computer does not automatically render the claims patent-ineligible. *Diehr*, 450 U.S. at 187 ("[A] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer."); *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1257 (Fed. Cir. 2014) (holding claims patent eligible when they "do not merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet"). Likewise here, the asserted claims are directed to methods that utilize a specially-programmed, centralized computer that implements specific controls, prospectively assesses risks associated with teratogenic drugs, and communicates that assessment to healthcare professionals in the form of generated prescription approval codes. This specific application—to the extent that the claims involve an abstract idea at all (which Celgene contests)—is patent eligible.

(b) The Inventions Cannot Be Performed Entirely In the Human Mind, Or By A Human Using A Pen and Paper

The claimed prescription approval codes cannot be generated by a medical professional armed with only his judgment, pen, and paper, as Lotus contends. *See, e.g.*, D.I. 69-1 at 7. Rather, a central computer specially configured to generate a prescription approval code is itself

an improvement upon computer function—not something that a medical professional can do by hand. *See* '720 patent at 13:18-14:3; 16:17-47.

Nonetheless, Lotus asserts that "the Federal Circuit has treated analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category." D.I. 69-1 at 18 (quotation omitted) (citing *Elec. Power Grp.,* 830 F.3d at 1353; *Cybersource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1372 (Fed. Cir. 2011)). But the "mental process" exception invoked by Lotus is narrowly limited to claims that can ***entirely*** be performed in the human mind, or using pen and paper. For instance in *Cybersource*, the claims were found unpatentable because "***[a]ll*** of [the] method steps can be performed in the human mind, or by a human using a pen and paper." 654 F.3d at 1372 (emphasis added). The court made explicit that claims where "the use of a computer is required to perform the claimed method" cannot, "as a practical matter, be performed entirely in a human's mind." *Id.* at 1376. Here, the claims of the REMS Patents on their face cannot be performed by a human or using pen and paper, as they expressly recite a machine—the centralized computer storage medium—that operates on stored data by performing risk assessments and then generating prescription approval codes based on those assessments. Thus, each claim recites explicit hardware and software implementation on a specially configured machine, which makes the "mental process" test inapplicable.

Lotus also relies on *SmartGene, Inc. v. Advanced Biological Labs.*, 555 Fed. App'x 950, 955 (Fed. Cir. 2014), and asserts that the REMS Patents "do no more than call on a 'computer readable storage medium,' with basic functionality for comparing stored and input data and rules, to do what doctors and pharmacists do routinely." D.I. 69-1 at 19-21. But in *SmartGene*, the claimed method (1) provided patient information to a computer device that (2) generated a

ranked listing of available therapeutic treatment regimens and (3) generated advisory information. 555 Fed. App'x. at 954-55. The claim did not "purport to identify ***any steps*** beyond those which doctors routinely and consciously perform." *Id.* at 955 (emphasis added). Therefore, the Federal Circuit expressly "limited" its ruling "to the circumstances presented [by the case], in which ***every*** step is a familiar part of the conscious process that doctors can and do perform in their heads." *Id.* (emphasis added).

By contrast, each of the REMS Patents recite the use of a ***centralized*** computer database that compiles all available information on a patient—including information unknown to a prescribing physician—and then generates prescription approval codes based upon specified risk assessments recited in the claims. Doctors could not compile such a vast network of information in their heads, could not process it, and could not generate an approval code in order to communicate the results of that assessment to any other healthcare professional who needed it.

In fact, a doctor's inability to consider and process the vast amounts of information that the claimed computer systems process created problems identified in the REMS Patents' specifications. The intrinsic record of the REMS Patents makes clear that because information pertaining to all prescribers, pharmacies, and patients is ***centrally*** stored, the claimed methods and systems enhance patient safety by accounting for risks of which one medical professional (or a de-centralized computer system) performing an ordinary risk assessment may not have otherwise been aware. For example, the specifications explain that another drug prescribed "by another physician whom the patient might visit, may interfere with the initial treatment regimen prescribed by the registered prescriber." *See* '720 Patent at 17:37-41. In that instance, the prescriber of the teratogenic drug may not know of the other prescription. But because practicing the claimed methods or utilizing the claimed systems ensures that all information

pertaining to the patient is centrally stored, the prescription approval code "will not be generated without further modification of the dosage of the [other drug]." *Id.* at 17:58-66.

The REMS Patents explain that in this way, the claimed methods "may be advantageously utilized to maintain the proper dosing of one or more drugs, to minimize the likelihood of the occurrence of an adverse side effect from the concomitant use of such drugs . . . and to assist in generating patient compliance with treatment protocols. . . ." *Id.* at 17:66-18:10. The same goes for the other risk assessments captured by the claims.

As such, because not every step of the claimed method can be mentally performed by a medical professional, *SmartGene* is inapposite by its own terms. Moreover, Lotus oversimplifies the claimed methods and systems, which are directed to far more than simply restricting access to certain drugs to certain individuals. For this reason alone, Lotus's motion should be denied.

2. The REMS Patents Do Not Preempt Any Abstract Ideas

Abstractness is a high threshold. The Federal Circuit has held that invalidating a claim under 35 U.S.C. § 101 on the basis of abstractness requires a strong showing:

> [T]his court also will not presume to define "abstract" beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.

Research Corp. Techs. v. Microsoft Corp., 627 F.3d 859, 868 (Fed. Cir. 2010). As such, the court's analysis should focus on "whether the claims preempt the use of the [abstract idea]." *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922, 930 (N.D. Cal. 2014). Despite Lotus's implication that preemption is irrelevant to the Court's analysis (*see* D.I. 69-1 at 11-12), the Federal Circuit has made clear—in cases post-dating the one decision that Lotus cites—that Lotus's implication is wrong. *See Amdocs*, 841 F.3d at 1302, 1306 (reversing Section 101 invalidity and finding the claims "not so broadly described to cause preemption concerns" and

"narrowly drawn to withstand preemption concerns"); *McRO, Inc. v. Bandai Namco Games Am., Inc.*, 837 F.3d 1299, 1316 (Fed. Cir. 2016) (reversing Section 101 invalidity and holding claims patent eligible because they "d[id] not preempt approaches that use rules of a different structure or different technique"). Lotus has not come close to making a showing of preemption.

A REMS is a drug safety program that the FDA can require for certain medications to help ensure that its benefits outweigh its risks.[5] There are 74 FDA-approved REMS, only three of which relate to drugs manufactured or marketed by Celgene.[6] The specific requirements of each REMS are different, taking into account the unique nature of the drug's risks and the likely setting in which it will be used.[7] For example, a REMS may require practices that support the safe use of the medication. A specific example might involve a drug that can cause a severe allergic reaction immediately after administration. In that instance, a REMS may be required to ensure the drug is administered only in a healthcare facility with personnel trained to manage severe allergic reactions. Another specific example might be to ensure certain lab testing is completed and the results are checked before a prescription is refilled. Other REMS may mitigate risks by educating healthcare providers about which patients may be at the greatest risk of experiencing an adverse event and who, therefore, should not be prescribed a medication.

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[5] *See, e.g.*, *Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm (last visited Sept. 07, 2018). This Court may take judicial notice of the FDA's website at this stage of the proceedings. *See, e.g.*, *Desai v. Sorin CRM USA, Inc.*, No. 12-2995, 2013 WL 163298, at *4 (D.N.J. Jan. 15, 2013) (explaining, in context of deciding Rule 12(c) motion, that "[t]his Court takes judicial notice of the FDA's website").

[6] *See, e.g.*, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/rems/ (last visited Sept. 07, 2018).

[7] *See, e.g.*, *Roles of Different Participants in REMS*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/DrugSafety/REMS/ucm592662.htm (last visited Sept. 07, 2018).

Celgene's REMS Patents do not come close to claiming ***all*** methods of "restricting access to pharmaceuticals by patients who may be harmed by the drug," as Lotus asserts in its motion. *See* D.I. 69-1 at 6. Many other patents are listed in the Orange Book for REMS on drug products that are not manufactured by Celgene.[8] This is possible only because Celgene's REMS Patents claim novel and specifically defined computerized methods and systems for monitoring and controlling the distribution of teratogenic drugs—not ***all*** methods for doing so. For example, the '531 Patent, which is dated January 7, 2014, is the last REMS Patent to issue. Months later, a patent issued to Jazz Pharmaceuticals, Inc. that explicitly claims methods of selectively blocking shipments of a prescription drug to a patient. *See, e.g.*, U.S. Patent No. 8,731,963.[9] The Celgene REMS Patents therefore cannot claim the abstract concept of "restricting access to pharmaceuticals," as Lotus alleges, if other companies can practice ***and patent*** that same alleged idea. *See Genetic Techs.*, 24 F. Supp. 3d at 931 (denying motion to dismiss because "[g]iven the alleged availability of alternative methods of genomic analysis, clear and convincing evidence is lacking that the '179 patent impermissibly ties up the relevant field").

Further, in *DDR*, the Federal Circuit rejected a Section 101 challenge to claims directed to systems and methods of generating composite web pages for electronic commerce websites. 773 F.3d at 1258-59. The Court recognized that "the claims address a business challenge," but nevertheless concluded that they did not "recite a fundamental economic or longstanding

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[8] *See* U.S. Pat. No. 8,112,290 (Entereg); U.S. Pat. No. 8,645,160 (Entereg); U.S. Pat. No. 7,765,106 (Xyrem); U.S. Pat. No. 7,765,107 (Xyrem); U.S. Pat. No. 7,895,059 (Xyrem); U.S. Pat. No. 8,457,988 (Xyrem); U.S. Pat. No. 8,589,182 (Xyrem); U.S. Pat. No. 8,731,963 (Xyrem). Moreover, in deciding a motion to dismiss, the Court may take judicial notice of these patents, which are public records. *See Int'l Bus. Machines Corp. v. The Priceline Grp. Inc.*, No. 15-137, 2016 WL 626495, at *20 n.18 (D. Del. Feb. 16, 2016).

[9] Although claims 24, 26, and 27 of U.S. Patent No. 8,731,963 were deemed unpatentable following *inter partes* review, claims 1-23, 25, and 28 remain in force, many of which claim "controls for distribution of the prescription drug." *See, e.g.*, U.S. Patent No. 8,731,963 at 9:59-61.

commercial practice" and were patent eligible. *Id.* at 1257. Specifically, the Court noted that "the claims at issue do not attempt to preempt every application of the idea . . . [r]ather, they recite a specific way to … solve a problem [in the art]." *Id.* at 1259. The same is true of the REMS Patents' asserted claims. They do not "merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet." *Id.* at 1257. The generation of a prescription approval code from a system built around a centralized computer storage medium designed to store ***all*** patient and prescriber information, monitor distribution, and detect potential risks associated with teratogenic drugs, is not a fundamental or longstanding economic or commercial practice. The specifications indicate that while computer storage media existed in the art to prevent certain individuals from receiving drugs, "[i]mprovements" to those systems were needed "to minimize and simplify the demands on the pharmacy, thereby improving compliance with the system of distribution, and reducing the risk that the drug will be dispensed to a contraindicated individual." *See* '720 Patent at 2:8-12. That improvement came in the form of improved computer functionality and the prescription approval code.

Accordingly, because the REMS Patents do not preempt all methods of restricting access to pharmaceuticals to certain individuals, they are not invalid under Section 101.

3. Lotus Inappropriately Analyzes Only "Representative Claims"

Lotus contends that the patentability of the REMS Patents can be decided by analyzing only three "representative claims." *See* D.I. 69-1 at 15. But the Federal Circuit has never held that one or more representative claims may always be used in the context of a Section 101 patent eligibility analysis; rather, the Federal Circuit approved the use of representative claims ***only*** when "the claims are substantially similar and linked to the same abstract idea." *Content Extraction*, 776 F.3d at 1348 (internal quotation marks omitted). Here, the five REMS Patents

contain 147 claims, 144 of which have been asserted in this action. And contrary to Lotus's assertion, the claims of the REMS Patents are not "substantially similar and linked to the same abstract idea." *See* D.I. 69-1 at 15 (quotation omitted).

While the inventions claimed in the REMS Patents share common features, the methods and systems claimed in each patent utilize those features in different ways, thus rendering a "representative claim" analysis inappropriate. None of the claims of the REMS Patents are directed solely to the abstract idea of restricting access to pharmaceuticals. For instance, the '720 Patent claims methods of avoiding the side effects of teratogenic drugs by ensuring that the computer readable storage medium generates a prescription approval code only after determining, amongst other things, that the prescriber, pharmacy, and patient are all registered and approved to dispense or take the drug. The '977 and '784 Patents claim methods of ensuring that the risks of teratogenic drugs are reduced by allowing a pharmacist to dispense the drug only after he has retrieved a prescription approval code from a computer readable storage medium, wherein the code is generated (or not) after a detailed risk assessment (the unique parameters of which are set forth in the claims). The '886 Patent claims methods of preventing a male patient taking a teratogenic drug from exposing a fetus to the drug. And the '531 Patent claims a system that a pharmacist may use to access a prescription approval code from a computer readable medium, wherein that system comprises, among other things, a "generator configured to generate a prescription approval code" and "an interface configured to send an on-line transmission to the pharmacist including the generated prescription approval code." *See, e.g.*, '531 Patent at 18:9-46. The claimed "generator" and "interface" are software and hardware components specifically designed to generate and transmit prescription approval codes, only after the programmed risk

assessments have been performed. The '531 Patent also claims methods of using the claimed system.

Lotus does not assess these specific and unique inventive concepts. For example, while Lotus's attorneys argue that the "generator" and "interface" were "well known in the industry" (D.I. 69-1 at 32) in an attempt to show that the Court need not undertake a detailed analysis of the claims, there is ***nothing*** to support Lotus's attorney argument. It should be rejected just like Lotus's other unsupported claims.

B. Lotus Fails To Show That The REMS Patents Do Not Claim An Inventive Concept

Because the claims of the asserted patents are not directed to an abstract idea, the Court may end the Section 101 inquiry here and find the claims patent eligible. *See Alice*, 134 S. Ct. at 2355. But if the Court determines that the REMS Patents claim an abstract idea, then it must proceed to step two of the eligibility analysis. Even when claims are deemed to be directed to an abstract idea, they are still patent eligible if they embody an inventive concept by reciting a "specific, discrete implementation of the abstract idea." *See Bascom Glob. Internet Servs., Inc. v. AT & T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016). At step two, the court should "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent eligible application." *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1297). The Federal Circuit has explained that the second step is satisfied when the claim limitations "involve more than performance of 'well-understood, routine, [and] conventional activities previously known to the industry.'" *Berkheimer*, 881 F.3d at 1367 (citations omitted) (alteration original).

"[W]hether a claim element or combination is well-understood, routine, and conventional is a question of fact," and this "inquiry falls under step two in the § 101 framework." *Aatrix*, 890

F.3d at 1359. Moreover, "[t]he mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional." *Berkheimer*, 881 F.3d at 1369. To that end, "improvements in the specification, to the extent they are captured in the claims, create a factual dispute regarding whether the invention describes well-understood, routine, and conventional activities," which renders a judgment of ineligibility inappropriate at this stage of the litigation. *Id.*

1. The REMS Patents Recite Specially-Designed Methods And Systems To Solve A Problem In The Art

Each asserted claim of the REMS Patents recites the generation of a prescription approval code by a centralized computer storage medium. The different claims of each REMS Patent recite specific rules that result in systems or methods able to perform varied risk assessments. The claimed elements, both individually and as an ordered combination, are not merely well-understood, routine, or conventional activities. Lotus presents no evidence to the contrary.

Lotus retorts that "[t]he inclusion of the 'prescription approval code' in the claims . . . is insufficient . . . because the code is itself abstract." D.I. 69-1 at 24. But where the use of computer code "achieve[s] an improvement in computer functionality," the Federal Circuit has found claims directed to such uses patent eligible. *See Amdocs*, 841 F.3d at 1301. Moreover, the prescription approval code here is not "simply an identifier of the outcome of the other abstract processes of the claims," as Lotus asserts. D.I. 69-1 at 25. Instead, the claimed systems' ability to generate a prescription approval code is an advancement over the prior art. Lotus has not presented ***any*** evidence that the specifically claimed prescription approval code can be found in the art. Similarly, Lotus has failed to show that the prescription approval code is not particularly tied to the centralized computer storage medium. As in *Amdocs*, because the claimed methods of the REMS Patents purposefully include this novel component "in a distributed architecture to

achieve a technological solution to a technological problem specific to computer networks," the claims are patent eligible. 841 F.3d at 1301.

Lotus's next argument—that the REMS Patents fail to recite patent eligible subject matter because they purportedly fail the "machine-or-transformation test" (D.I. 69-1 at 26)—reflects a fundamental misunderstanding of the test under Section 101. *Prompt Med. Sys., L.P. v. Allscripts Mysis Healthcare Solutions, Inc.*, No. 6:10-cv-71, 2012 WL 678216 (E.D. Tex. Feb. 13, 2012), is instructive. There, the patent-in-suit was "directed to a method for computing Current Procedural Technology ('CPT') codes from physician-generated documentation." *Id.* at *1. The court held that the patented method did not satisfy the machine or transformation test, but denied a Rule 12(b)(6) motion seeking a declaration that the patent claimed ineligible subject matter because the claimed code-generating method—like the methods claimed in Celgene's REMS Patents—improved upon problems known in the art. The court explained:

> [P]rior solutions typically required the CPT code to be determined after the physician—patient encounter was complete. Prompt's improvements are for more than an improved algorithm. They include determination of a code during the physician—patient encounter and eliminate the need for coders to pore over books, summary cards, and notes to determine a CPT code after the physician—patient encounter is complete.

Id. at *8. Moreover, the court held it was immaterial that the specifications of the patents did not set forth an algorithm responsible for achieving this improvement. Indeed, "the patentability of the instant claims does not turn on the presence or absence of a detailed algorithm for computing the CPT codes." *Id.* at *7.

Likewise here, the claimed methods improve upon the prior art systems by generating a prescription approval code based upon an analysis of data stored in a central computer storage medium that eliminates the need for prescribers and distributors of a drug to pore over patient records (which may not even be available without the claimed computer system). This not only

increases patient safety, but also represents a patentable improvement over known computerized drug distribution systems.

The Federal Circuit's decision in *McRO* further supports the patentability of the inventions claimed in the REMS Patents. Even assuming, *arguendo*, that Lotus's "general-purpose computer" argument (*see, e.g.*, D.I. 69-1 at 26) is correct (which Celgene disputes), the Federal Circuit has held that rules implemented using computer software on general-purpose computers are patent eligible where there is "no evidence that the process previously used by [those in the field] is the same as the process required by the claims." *McRO*, 837 F.3d at 1314. That is the case here. Notably, Lotus fails to present ***any*** evidence of what methods were used in the art prior to the REMS Patents. By incorporating the specific rules as claim limitations, the REMS Patents here, like the patent in *McRO*, are "limited to a specific process . . . using particular information and techniques and do[] not preempt approaches that use rules of a different structure or different technique." *Id.* at 1316.

2. The Parties Dispute Whether The Claimed Elements Of The REMS Patents Are Well-Understood, Routine, And Conventional Activities, Rendering Judgment Inappropriate At This Stage

The Federal Circuit's recent decisions in *Berkheimer* and *Aatrix* confirm that ***any*** genuine dispute over whether the asserted claim elements, alone or in combination, constitute well-understood, routine, and conventional activities raises factual issues that cannot be resolved without a fully developed record, rendering judgment on the pleadings inappropriate. In *Berkheimer*, the Federal Circuit reversed a finding of summary judgment as to certain claims because there was "a genuine issue of material fact in light of the specification regarding whether [the claims] archive documents in an inventive manner that improves these aspects of the disclosed archival system . . . making summary judgment inappropriate with respect to these claims." 881 F.3d at 1370.

In *Aatrix*, the court applied this same principle to overturn a judgment on the pleadings. There, the Federal Circuit held that the plaintiff's "allegations at a minimum raise factual disputes underlying the § 101 analysis, such as whether the claim term 'data file' constitutes an inventive concept, alone or in combination with other elements, sufficient to survive an *Alice*/*Mayo* analysis at the Rule 12(b)(6) stage." 882 F.3d at 1126. Following that guidance, numerous district courts have denied motions to dismiss where factual disputes cloud the question of whether the patents in question claim an inventive concept. *See, e.g.*, *Pure Data Sys., LLC v. Ubisoft, Inc.*, No. 18-cv-00852, 2018 WL 3417530, at *11-12 (N.D. Cal. July 13, 2018); *T-Jat Sys. 2006, Ltd. v. Expedia, Inc.*, No. 16-581, 2018 WL 1525496, at *7 (D. Del. Mar. 28, 2018).

Here, the parties dispute whether the REMS Patents contain a transformative inventive step. Lotus claims that they do not (*see* D.I. 69-1 at 12-13), while Celgene contends that the REMS Patents claim novel and inventive methods not found in the prior art for at least the reasons set forth above.

Lotus's assertions that no factual disputes exist are a transparent end-run around the Federal Circuit's decisions in *Berkheimer* and *Aatrix* and can be summarily dismissed. First, Lotus asserts that the claimed inventions "merely use a computer to automate a task that is routinely manually performed by health care professionals." D.I. 69-1 at 22. This argument, however, is rooted in Lotus's litigation-driven oversimplification of Celgene's inventions and fails to take into the account the actual benefits of practicing the claimed methods, as explained above. *See supra*, § III(A)(1)(a)-(b). The claimed methods do not simply automate the ordinary practice of healthcare professionals—they significantly approve upon those practices. Moreover, Lotus entirely overlooks that the centralized computer readable medium's ability to generate a

prescription approval code is not found in the art, and is itself an improvement upon computer function that renders judgment inappropriate.

Next, Lotus incorrectly argues that the REMS Patents "do not identify any benefit in the disclosed computer technology itself but instead assert that the inventive aspect of the claims is increased efficiency for a pharmacy[,]" and that the "there is nothing inventive about using a computer for the sole purpose of doing something more quickly or increasing the efficiency of something a human would otherwise accomplish." D.I. 69-1 at 23 (citing *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363 (Fed. Cir. 2015)). But the claimed methods are not directed solely to increasing efficiency. Instead, by linking together all prescribers, distributors, and users of a drug through an inventive centralized system that allows for the administration of the drug only when a prescription approval code is generated, patient safety is improved. *See* '720 Patent at 2:9-12; 2:40-45; 3:5-11; 11:31-38; 13:65-14:3. The specification makes clear that "the methods of the present invention may operate more efficiently, ***leading to better compliance, and hence decreased risk that the adverse side effect will occur***." *Id.* at 10:35-40 (emphasis added).

Moreover, it is clear from the specification that when healthcare professionals practiced the prior art, they were often unaware of and unable to account for certain risks. *See id.* at 17:61-18:10. The claimed methods eliminate that risk by improving then-existing computer systems with "unconventional technological solution[s]," rendering the claims patent eligible. *Amdocs*, 841 F.3d at 1300; *Bascom*, 827 F.3d at 1350. As such, the claimed inventions contain "an inventive concept . . . sufficient to survive an *Alice*/*Mayo* analysis at the [motion to dismiss] stage." *Aatrix*, 882 F.3d at 1126.

3. Disputes Over Claim Construction Also Render Judgment Inappropriate At This Stage

Courts in this District routinely deny Section 101 motions where claim terms are in dispute. Where "the parties vigorously dispute the basic character and meaning of the claims, then the Court will be unable to fairly apply the *Alice* test, especially at the inventive concept stage." *Eagle View Techs., Inc. v. Xactware Sols., Inc.*, No. 15-7025, 2016 WL 4154136, at *3 (D.N.J. Aug. 2, 2016) (quotation omitted) (citing *WAG Acquisition*, 2015 WL 5310203, at *6); *see also Data Distribution*, 2014 WL 4162765, at *8 ("Given the density of the '908 Patent with its 100 claims . . . and the lack of Plaintiff's proposed constructions or any agreement about claim construction, the Court finds it is advisable to postpone adjudication of the '908 Patent's eligibility under the abstractness test.").

Here, although Lotus has agreed to "utilize Celgene's construction of 'prescription approval code' from the *inter partes* review" (D.I. 69-1 at 24 n.8), the parties have ***not*** agreed to any construction of the terms "computer readable storage medium," "computer readable medium," and "a generator configured to generate a prescription approval code." Construction of each of these terms will be necessary for the Court to determine whether the REMS Patents claim an inventive concept. For example, if the Court construes "computer readable storage medium" and "computer readable medium" to mean "a centralized database that includes all registration information regarding the claimed prescribers, pharmacies, and patients," as Celgene proposes, that construction will support the conclusion that Celgene has, in fact, claimed a centralized storage media that improves upon the art by solving an identified problem.

Moreover, the parties (and the Court) have not reached an understanding regarding the definition of "a generator configured to generate a prescription approval code." Celgene posits that the plain meaning of "generator" is software specifically coded to generate a prescription

approval code. The Court will need to determine what a "generator" is in order to determine if claims embodying this limitation recite well-understood, routine, and conventional activities. And this Court and courts in this Circuit routinely allow the parties to develop a factual record before they can truly decide whether the patents-in-suit claim improvements to computer function. *See, e.g.*, *Priceline Grp.*, 2016 WL 626495, at *13 (denying motion to dismiss without prejudice where factual "issues relating to innovation and preemption ... would need to be further fleshed out prior to a final decision"); *Synchronoss Techs., Inc. v. Hyperlync Techs., Inc.*, No. 15-2845, 2016 WL 868920, at *4 (D.N.J. Mar. 7, 2016) ("a dispute concerning the area of technology addressed in the Patents In Issue is not conducive to a resolution on a motion to dismiss at the initial stages of litigation").

Lotus's failure to offer any definition of "computer readable storage medium," "computer readable medium," and "a generator configured to generate a prescription approval code" in its motion "makes clear that the parties dispute the proper interpretation of the claims, such that the Court [may] find[ ] itself unable to develop a full understanding of the basic character of the claimed subject matter." *Eagle View*, 2016 WL 4154136, at *3 (quotation and citation omitted). Moreover, for the Court to "invalidate [the patents-in-suit] on subject matter eligibility grounds before claim construction, then ***Defendants must 'establish*** that the only plausible construction [i]s one that . . . render[s] the subject matter ineligible (with no factual inquiries).'" *Data Distribution*, 2014 WL 4162765, at *6 (emphasis added). Lotus has not met its burden, and this dispute provides yet another independent reason for the Court to deny Lotus's motion.

IV. CONCLUSION

For the reasons stated above, Celgene respectfully requests that Lotus's motion be denied.

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Respectfully submitted,

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
973-286-6700
clizza@saul.com

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
Marta A. Godecki
Brian J. Forsatz
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

Anthony M. Insogna
Cary Miller, Ph.D.
Matthew J. Hertko
JONES DAY
4655 Executive Drive
San Diego, CA 92121
(858) 314-1200